UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re: BAIR HUGGER FORCED AIR WARMING DEVICES PRODUCTS LIABILITY LITIGATION This Document Relates To: All Actions	MDL No. 15-2666 (JNE/FLN) **JOINT OPPOSITION OF NONPARTY VITAHEAT MEDICAL, LLC AND DEFENDANTS TO PLAINTIFFS' MOTION TO OVERRULE VITAHEAT'S RELEVANCE OBJECTION**

VitaHEAT Medical, LLC ("VitaHEAT") is a small medical device company that manufactures a conductive patient warming device called the VitaHEAT® UB3 system. Plaintiffs' subpoena to VitaHEAT demands that VitaHEAT produce the majority of its corporate records relating to the UB3 system, including all documents relating to design, testing, and marketing, communications with regulators and medical professionals, as well as documents relating to 3M's recent agreement to distribute the UB3 system. Plaintiffs contend these documents are relevant because the UB3 system is (they now claim) a feasible safer alternative design to the 3M™ Bair Hugger™ patient warming system. Pl. Mem. at 8. Plaintiffs' motion to overrule VitaHEAT's relevance objection should be denied because the UB3 system is a substantially different product, and overwhelming case law holds that a substantially different product may not be used to

establish an alternative feasible design – even when the other product has the same general purpose as the allegedly defective product.[1]

Federal and state courts across the country have consistently held that plaintiffs "cannot demonstrate the existence of a safer alternative design by pointing to a substantially different product, even when the other product has the same general purpose as the allegedly defective product." *Massa v. Genentech Inc.*, No. H-11-70, 2012 WL 956192, at *7 (S.D. Tex. Mar. 19, 2012) (concluding as a matter of law that competitors' psoriasis treatments were substantially different products, not alternative designs to the defendant's product); *see also Tersigni v. Wyeth*, 817 F.3d 364, 368 (1st Cir. 2016) (holding that the plaintiff must show "the product in question could have been more safely designed, not that a different product was somehow safer"). While the UB3 system and the Bair Hugger system serve a similar general purpose – to warm patients – they do so using fundamentally different types of technology. The UB3 system employs *conductive* warming (*i.e.*, heat transferred by direct contact such as an electric heating pad), whereas the Bair Hugger system employs *convective* warming (*i.e.*, heat transferred by movement of warm air). As explained in the accompanying Declaration of Al Van

[1] Even though Plaintiffs' subpoena does not seek discovery directly from 3M, 3M has its "own right to reasonable discovery and efficient disposition of the case." *Shukh v. Seagate Tech., LLC*, 295 F.R.D. 228, 236 (D. Minn. 2013). Plaintiffs' expansive requests to VitaHEAT are an attempt to open the floodgates of discovery on new topics and another product that have no relevance to the Bair Hugger litigation. This will not only increase 3M's cost to defend itself in this case, but it also threatens the annoyance and harassment of 3M's business partner, resulting in a potential chilling effect on their willingness to work with 3M in the future.

Duren, the conductive warming technology used in the VitaHEAT UB3 cannot be incorporated into the Bair Hugger's convective warming system.

Thus, contrary to Plaintiffs' assertion, this is nothing like the situation Judge Ericksen faced in *Krumm v. Bar Maid Corp.*, No. 11-2782, 2013 WL 3064442, at *6 (D. Minn. June 18, 2013), where the plaintiffs argued that the defendant should have incorporated a safety feature of one of its electric glass washers into another of its electric glass washers, and the defendant conceded that the modification was possible and objected only to the cost. There, the plaintiffs appropriately argued that the *product in question* could have been more safely designed, not (as Plaintiffs do here) that a *different* product was somehow safer.

Plaintiffs' motion should also be denied on an additional basis. VitaHEAT never agreed to have its relevance objection ruled upon in a vacuum, without regard to its burden and confidentiality objections. As explained in the accompanying declaration of VitaHEAT's commercial operations manager, VitaHEAT's small staff cannot, even with the assistance of outside counsel, produce the documents demanded by Plaintiffs without enormous hardship and a severe impact on their day-to-day business. Moreover, Plaintiffs seek the production of documents that, if disclosed to Plaintiffs' ally (and VitaHEAT's conductive warming competitor), Dr. Augustine, are likely to cause enormous and irreparable competitive harm. The burden and risk faced by VitaHEAT in complying with Plaintiffs' subpoena thus far outweighs any (non-existent) benefit to the litigation in the production of irrelevant documents. Fed. R. Civ. P. 26(b)(1).

BACKGROUND

I. VitaHEAT's UB3 System and 3M's Bair Hugger System Are Different Products that Use Fundamentally Different Patient-Warming Technologies.

VitaHEAT is a startup medical device company based in Rolling Meadows, Illinois. It manufactures the UB3 Patient Warming System. The UB3 system is a *conductive* warming system. Declaration of Al Van Duren ("Van Duren Decl.") ¶ 5. With conductive warming, heat is transferred by direct surface to surface contact. The UB3 is a thin, underbody mattress that uses patented conductive ink technology to transfer heat directly from the underbody mattress to a patient's skin. *Id.* ¶¶ 5, 7.

As Plaintiffs note, VitaHEAT states in its 510(k) summary filed with the FDA that its device "is considered to be substantially equivalent to the predicate device HotDog Patient Warming Mattress System by Augustine Biomedical & Design LLC." Pl. Mem. Ex. Q at 5. Augustine's HotDog system also employs conductive (heat transfer by direct surface to surface contact) warming technology.[2]

Unlike the UB3 and HotDog systems, the 3M Bair Hugger system is a *convective* warming system (*i.e.*, a system that transfers heat through the movement of warm air).

[2] This Court denied Defendants' motion to compel against Augustine to produce HotDog-related documents because Plaintiffs had declined to take the position that the HotDog was a feasible safer alternative design to the Bair Hugger system, even though (like the VitaHEAT UB3) it is a conductive warming system. ECF No. 148 at 3. While Defendants' primary basis for seeking HotDog-related documents was to demonstrate Augustine's bias and lack of credibility on scientific issues (*see* ECF No. 130 at 35), 3M did also cite the issue of alternative design in its briefing. Defendants recognize that they were incorrect to make that argument (and the Court properly rejected it at the time), because any product incorporating conductive warming technology is substantially different from the Bair Hugger system and therefore, as a matter of law, cannot qualify as a feasible safer alternative design.

Van Duren Decl. ¶ 4. With convective warming, heat is transferred from warm air to a surface. The Bair Hugger warming unit generates temperature-controlled warm air, which is then delivered into a blanket with small perforations. Heat transfer is accomplished through the gentle dispersion of warmed air through the small perforations in the Bair Hugger blanket across the patient's skin. *Id*.

Thus, the Bair Hugger system's convective warming technology is fundamentally different from the UB3 system's conductive warming technology. The VitaHEAT statements and marketing materials cited by Plaintiffs reinforce this point. Pl Mem. n.46, 52. As a result of this fundamental technological difference, the Bair Hugger system could not be modified to incorporate the UB3's conductive warming technology, any more than the UB3 could be modified to incorporate the Bair Hugger system's convective technology. Van Duren Decl. ¶ 6. Plaintiffs present no evidence, much less expert evidence, to the contrary.

II. 3M Entered Into a Distribution Agreement with VitaHEAT So It Could Offer a Mobile Complement to the Bair Hugger System.

On August 31, 2016, 3M reached an agreement with VitaHEAT to serve as the exclusive distributor of the UB3 system in the United States. While VitaHEAT does offer the UB3 system for use in operating rooms, 3M entered into the agreement for a different purpose. Unlike the Bair Hugger system, the UB3 system can be powered by batteries, meaning that it can be used in mobile settings where no power outlet is available, as shown in the image below from VitaHEAT's website:

See http://vitaheatmedical.com/wp-content/uploads/2016/12/preoperative-n.png.

As 3M explained in its press release announcing the distribution agreement, 3M partnered with VitaHEAT to "complement [the Bair Hugger system] offering with mobility – while patients are being moved to and from the OR, for example – to help avoid hypothermia by providing continuous patient warming." Pl. Mem. Ex. C. Thus, despite Plaintiffs' rank speculation, 3M did not enter into the distribution agreement with VitaHEAT to offer an "alternative" to the Bair Hugger system for the operating room. Indeed, Plaintiffs concede that they deposed "key 3M employees" and none of them said that the purpose was anything different than what 3M said in its press releases: to offer a mobile patient warming product as a complement to the (non-mobile) Bair Hugger system.[3] Pl. Mem. at 5.

[3] 3M rejects any implication that 3M's distribution agreement with VitaHEAT was prompted by a lack of confidence in the safety of the Bair Hugger system. The safety of the Bair Hugger system is well established, and not one scientific study has ever

III. Plaintiffs' Subpoena Seeks to Impose an Untenable Burden and an Intolerable Competitive Risk to VitaHEAT.

Plaintiffs' subpoena demands documents in 26 extraordinarily broad categories. Pl. Mem. Ex. N. It requests documents relating to the design, testing, and regulatory clearance of the UB3 system (requests 1-12); documents relating to the relationship and distribution agreement between VitaHEAT and 3M (requests 13-18, 25-26); documents relating to communications with third-party medical professionals, researchers, scientists, government agencies, and industry organizations (requests 19, 21-22); documents relating to marketing efforts for the UB3 system (request 20); and documents concerning the identities and financial interests of VitaHEAT's leadership (requests 23-24). Put simply, Plaintiffs are asking for the majority of VitaHEAT's corporate records concerning its commercialized product.

Even with the assistance of outside counsel, VitaHEAT will face an untenable burden if it is forced to respond to these broad requests. VitaHEAT has only eleven staff members. *See* Declaration of William T. Renwick ("Renwick Decl."), VitaHEAT's Manager of Commercial Operations ¶ 4. Each of the eleven staff members carries great responsibility, already works full time or more than full time, and lacks the capacity to assist with major document collection and production efforts. *Id.* ¶¶ 13-20. Because the universe of potentially responsive information is so vast, compliance with the subpoena

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concluded that the Bair Hugger system causes or increases the risk of post-operative surgical site infections. The positions that Plaintiffs attempt to attribute to Mr. Van Duren are clearly rejected by Mr. Van Duren *in the very same documents Plaintiffs cite*. *See, e.g.*, Pl. Mem. Ex. D (Van Duren describes as "Crazy Town" and "outrageous" viewpoints of *Augustine* that Plaintiffs falsely attribute to Van Duren).

would necessarily require staff members to devote significant time to collection efforts, distracting them from their ordinary daily work obligations and preventing VitaHEAT from operating at the necessary capacity. *Id.* As explained in the Declaration of William T. Renwick, responding to these requests would require the full-time efforts of nearly 30 percent of VitaHEAT's work force for at least two to three weeks, even with the assistance of outside counsel. Renwick Decl. ¶ 16.

Moreover, compliance with the subpoena would force VitaHEAT to turn over trade secret and other confidential business information – including design, testing, regulatory, marketing and other information – to Kennedy Hodges LLP, a law firm not only representing Plaintiffs, but that also has been engaged in an ongoing business relationship with Dr. Augustine's HotDog business. *Id.* ¶ 23. The HotDog is another conductive patient warming device and one of the UB3's primary competitors. *Id.* ¶ 24. As this Court has noted, the relationship between Kennedy Hodges and Augustine began in 2009 and (according to Augustine) has "never been formally terminated." ECF No. 226 at 3 (quoting Augustine affidavit). VitaHEAT would be required to turn over highly sensitive information concerning its only commercially available product to the purported legal agents of one of its primary competitors, risking substantial and irreparable competitive harm.[4] The existing protective order does not provide adequate protection to prevent this harmful disclosure from occurring.

[4] This is no mere abstract risk. Just a few hours before this brief was filed, Augustine sent out an email "blast" to healthcare providers attacking the VitaHEAT UB3 in addition to repeating his usual attacks against the Bair Hugger system.

Plaintiffs refused to engage with VitaHEAT on its burden and confidentiality concerns, saying that such concerns should be deferred until this Court has resolved VitaHEAT and 3M's relevance objection. Declaration of Deborah E. Lewis ("Lewis Decl.") ¶¶ 4, 7. VitaHEAT disagreed with this approach, which improperly asks the Court to consider relevance in a vacuum. *Id.* ¶¶ 5, 7. Under Rule 26(b)(1), VitaHEAT's concerns must be taken into account in weighing whether to allow the discovery that Plaintiffs demand.

ARGUMENT

I. VitaHEAT and 3M's Relevance Objection Is Strongly Supported by the Overwhelming Weight of Case Law.

Under Rule 26(b)(1), a party may not take discovery that is irrelevant to the parties' claims or defenses. The amended Rule is consistent with longstanding Eighth Circuit law, which requires the proponent of the discovery to make a "threshold showing of relevance . . . before parties are required to open wide the doors of discovery," so as to limit "fishing expeditions in discovery." *Hofer v. Mack Trucks, Inc.*, 981 F.2d 377, 380 (8th Cir. 1992).

Plaintiffs have not made and cannot make that threshold showing of relevance. Their sole basis for asserting the relevance of the documents they seek from VitaHEAT is that the UB3 system is a "feasible safer alternative design" to the Bair Hugger system. That assertion is contrary to the overwhelming majority of case law from federal courts. This Court should therefore sustain VitaHEAT and 3M's relevance objection.

A. Courts Consistently Have Held That A Substantially Different Product Cannot Qualify as a "Feasible Safer Alternative Design."

Plaintiffs are correct that proof of a feasible safer alternative design is "the very heart" of a design defect case. Pl. Mem. at 10. Plaintiffs' analysis of what evidence is relevant to proving a feasible safer alternative design, however, is simply wrong and contrary to the overwhelming weight of case law in this District and other jurisdictions.

In Plaintiffs' view, a substantially different *product* can qualify as a feasible safer alternative design to the defendant's product so long as it is used for the same general purpose, is equally effective, and is (allegedly) safer. Plaintiffs note that the VitaHEAT UB3 is, like the Bair Hugger system, used to warm patients, and cite VitaHEAT's statements that the UB3 system is as effective at warming patients as forced-air warming technology. Pl. Mem. at 12.

Contrary to Plaintiffs' assertion, case law says that a substantially different product cannot qualify as a feasible safer alternative design. In the words of Judge Tunheim, plaintiffs "appear to confuse the existence of an alternative 'design' with an alternative 'product.'" *Burks v. Abbott Labs.*, Civil No. 08-3414 (JRT/JSM), 2010 WL 1576779, at *4 (D. Minn. Apr. 20, 2010) (concluding on defendant's motion to dismiss that liquid infant formula is not an alternative design for powder infant formula and noting that plaintiffs "appear to confuse the existence of an alternative 'design' with an alternative 'product'"). Courts have repeatedly held that a plaintiff "cannot demonstrate the existence of a safer alternative design by pointing to a substantially different product, even when the other product has the *same general purpose* as the allegedly defective

product." *Massa*, 2012 WL 956192, at *7 (emphasis added; internal quotation omitted). As the First Circuit has said, the plaintiff must show that "the *product in question* could have been more safely designed, not that a different product was somehow safer." *Tersigni*, 817 F.3d at 368 (emphasis added).[5]

In a footnote, Plaintiffs argue that *Massa* and the long line of cases it represents "flout the well-established fact that a safer design alternative may be implemented in

[5] *See, e.g.*, *Hosford v. BRK Brands, Inc.*, --- So.3d ---, 2016 WL 4417256, at *4-5 (Ala. Aug. 19, 2016) (holding as a matter of law that the dual-sensor smoke alarm design put forth by the plaintiff was a design for a "different product altogether," rather than an alternative design for an ionization smoke alarm, even though both were sold for the purpose of detecting smoke); *Hilaire v. DeWalt Indus. Tool Co.*, 54 F. Supp. 3d 223, 248-49 (E.D.N.Y. 2014) (concluding that even though they both cut wood, a trap saw is an "entirely different device" from a table saw, and therefore cannot be an alternative design)*; McCarthy v. Danek Med., Inc.*, 65 F.Supp.2d 410, 412 (E.D. La. 1999) (noting that alternative surgical methods for addressing spinal fusion, as compared to alternative designs for fixation devices, were not alternative designs for the purposes of a design-defect action); *Brockert v. Wyeth Pharms., Inc.*, 287 S.W.3d 760, 762, 769-71 (Tex. App. Hous. [14th Dist.] 2009, no pet.) (holding that Premarin was not an alternative design to Prempro but a different product, even though they had the same purpose of treating menopausal systems); *Clanton v. 3M Co.*, No. 251-12-970 (Miss. Cir. Ct. July 1, 2014), slip op. at *5 (attached to Lewis Declaration as Exhibit 2) (rejecting plaintiff's position that non-disposable elastomeric mask was an alternative design for 3M's disposable mask because the elastomeric mask was an "entirely different product"); *see also Simon v. Smith & Nephew, Inc.*, 990 F. Supp. 2d 395, 405 (S.D.N.Y. 2013) (holding that "an allegation that [defendant] could have manufactured a different product altogether, or that others have done so, does not itself make out a plausible claim of design defect"); *Michael v. Wyeth, LLC*, 2011 WL 2150112, at *11 (W.D.W.Va. May 25, 2011) ("an alternative design must not be an altogether essentially different product"); *Pinello v. Andreas Stihl Ag & Co. KG*, No. 08 CV 425, 2011 WL 1302223, at *16 (N.D.N.Y. Mar. 31, 2011) (holding that plaintiff's contention that an "entirely different product" could have been used did not create a dispute of material fact as to whether there was an alternative design); *Torkie-Tork v. Wyeth*, 739 F. Supp. 2d 895 (E.D. Va. 2010) ("[A]n alternative design is not reasonable if it alters a fundamental and necessary characteristic of the product."); *Kimball v. RJ Reynolds Tobacco Co.*, 2006 WL 1148506, at *3 (W.D. Wash Apr. 26, 2006) (finding that a plaintiff "cannot point to an entirely different product as an alternative design");

other products." Pl. Mem. at 14 n.50 (internal quotation marks omitted.) No "flouting" has occurred. *Of course* a plaintiff can point to a similar product that incorporates an additional safety feature, and then demonstrate that the defendant's product can also be reengineered to incorporate that additional feature. (That is what the plaintiffs did in *Krumm*, where the defendant only objected that incorporating additional safety features would raise the cost of their product and thereby make it less appealing to consumers.) The point is that a Plaintiff does not carry its burden when it identifies a *different product* that employs a fundamentally *different type of technology*, and argues that the defendant should ditch its current technology in favor of that different technology because it is allegedly safer. That is the rule recognized in *Massa*, *Burks*, and a multitude of other cases, and the rule is controlling here.

The Fifth Circuit's decision in *Theriot v. Danek Medical, Inc.*, 168 F.3d 253, 255-56 (5th Cir. 1999) is particularly instructive. In that case, the Fifth Circuit discussed the false assumption that underlies allegations like Plaintiffs are making here:

> [Plaintiff] claims that the product at issue here is a product whose purpose is to provide biomechanical stability. [Plaintiff] therefore argues that other products that do not use pedicle screws should be considered as alternative designs. . . . Underlying this argument is the assumption that . . . there can be no system using pedicle screws that would be an acceptable product. The problem with this argument is that it really takes issue with the choice of treatment made by [plaintiff's] physician, not with a specific fault of the pedicle screw sold by Danek.

Theriot v. Danek Medical, Inc., 168 F.3d 253, 255-56 (5th Cir. 1999).[6]

[6] *See also Caterpillar, Inc. v. Shears*, 911 S.W.2d 379, 385 (Tex. 1995):

The logic in *Theriot* applies with equal force here. Plaintiffs argue that the Bair Hugger system is a product whose purpose is to provide patient warming. Plaintiffs argue that other patient warming products that do not use convective warming should therefore be considered as alternative designs. Underlying this argument is the false assumption that there can be no system using forced air warming that would be an acceptable product. As the Fifth Circuit says, the problem with this argument is that it takes issue with the choice of treatment made by plaintiff's physician – to use convective warming versus conductive warming – not with a specific design fault of the Bair Hugger system.

In sum, overwhelming case authority sets forth the rule that an alternative design must be a *modification t*o the defendant's product, not a different product that employs a fundamentally different technology to address the same (or similar) clinical purpose. Plaintiffs' argument that the Bair Hugger system should use VitaHEAT's conductive warming technology, rather than convective warming, is not an argument that the Bair Hugger system should have been safer; rather, it is an improper argument that the Bair Hugger system should have been a different product. *See Massa*, 2012 WL 956192, at *7 ("Massa's argument that 'Raptiva could have been formulated with a number of

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> A motorcycle could be made safer by adding two additional wheels and a cab, but then it is no longer a motorcycle. A convertible can be made safer by fully enclosing the cab, but then it is just an ordinary car. The law of products liability demands that manufacturers and distributors take feasible steps to make their products reasonably safe. It is not rational, however, to impose liability in such a way as to eliminate whole categories of useful products from the market.

alternative underlying compounds' is not an argument that Raptiva should have been safer; it is an argument that Raptiva should have been a different product.").

B. None of Plaintiffs' Cases Supports Their Position.

Plaintiffs cite a handful of cases in purported support of their view that a substantially different product can be a feasible safer alternative design. In fact, none of the cases Plaintiffs cite supports that view.

Mentor. Plaintiffs rely very heavily on *In re Mentor Corp. Obtape Transoburator Sling Prods. Liab. Litig.*, No. 4:08-MD-2004 (CDL), 2010 WL 234797 (M.D. Ga. Jan. 14, 2010). Pl. Mem. at 10-11. It is impossible to see how anyone could read that decision as helpful to Plaintiffs, because relevance was not disputed. The plaintiffs subpoenaed R&D documents from a third party, Ethicon, on the basis that Ethicon's product (TVT) was a safer feasible alternative design to Mentor's vaginal mesh product ("ObTape"). Mentor *admitted* the relevance of the discovery sought by the plaintiff: the court noted that "Ethicon acknowledges that the design of TVT was an alternative design to ObTape." *Id.* at *2 (emphasis added). Indeed, in its 510(k) application to the FDA, Mentor had claimed that its product was the substantial equivalent of Ethicon's TVT. *Id.* at *3. The court therefore quickly moved past the issue of relevance and on to Ethicon's breadth, burden and privilege objections. Here, by contrast, 3M denies that the VitaHEAT UB3 is an alternative design to the Bair Hugger system. Neither VitaHEAT nor 3M has ever claimed that its product is the substantial equivalent of the other.

Krumm. Judge Ericksen's decision in *Krumm*, 2013 WL 3064442, also provides no support to Plaintiffs, and is consistent with the overwhelming authority supporting

VitaHEAT and 3M's relevance objection. *Krumm* involved an electric glass washer sold by Bair Maid. Plaintiffs argued that design features of another Bair Maid electric glass washer should have been incorporated into the A-200 to make it safer. Bar Maid moved for summary judgment, arguing that incorporating those changes would make the A-200 "significantly more expensive," but provided no supporting evidence. *Id.* at *6. Bar Maid never argued that it was impossible – or even difficult – to add these features. Judge Ericksen considered the cost issue to be relevant to whether the alternative design was feasible, but saw it as a fact issue for the jury, and therefore denied summary judgment to Bair Maid. *Id.* *Krumm* might be relevant if Plaintiffs were to argue that the Bair Hugger system could be modified to add additional safety features, and 3M were to respond that those modifications would be too costly. That is not the situation here.

Block. Plaintiffs cite Judge Montgomery's decision denying summary judgment in *Block v. Toyota Mot. Corp.*, 5 F. Supp. 3d 1047 (D. Minn. 2014). In that case, the design modification proposed by the plaintiffs to address the alleged risk of sudden acceleration in the 1996 model Toyota Camry was implemented by Toyota in the 2000 model Camry. *Id.* at 1067. The *Block* plaintiffs did not attempt to rely on a substantially different product (like a motorcycle or truck) as an alternative design, but rather an updated version of the very same product.

Broan Nutone. The Southern District of Mississippi's decision to deny summary judgment to the defendant in *Standard Fire Ins. Co. v. Broan Nutone, LLC*, No. 2:07cv44-KS-MTP (S.D. Miss. July 1, 2008) is similarly unhelpful to Plaintiffs. Standard Fire alleged that a fire broke out at its insured's home because the electric

bathroom ventilation fan manufactured by Broan did not include an adequate thermal protection device. Standard Fire's expert pointed to a major competitor of Broan that had utilized thermal protective devices in its electric fans for decades. *Id.* at *2. The court denied Broan's motion to exclude the expert's opinion, because Broan had submitted no evidence that incorporating a thermal protective device would destroy its fans' "utility, usefulness, practicability, and desirability." *Id.* at *5. In sum, plaintiffs' position was that an *additional* feature could be *incorporated into* Broan's products to make them safer, and Braun presented no evidence to the contrary.

Sec. Nat'l Bank. Next, Plaintiffs cite *Sec. Nat'l Bank of Sioux City v. Abbott Labs.*, No. 11-cv-4017 (DEO), 2012 WL 327863, at *10 (N.D. Iowa Feb. 1, 2012), for the proposition that there is no "magic line of demarcation whereby suggested alteration constitutes an alternative product rather than alternative design." Pl. Mem. at 14 n.50. In that case, the court's point in denying summary judgment to the defendant (a marketer of powdered infant formula) was that liquid infant formula *is* a modification to powdered infant formula. All that needs to be done to turn powdered formula into liquid formula is to add water, "one of the most ubiquitous substances on Planet Earth." *Id.* The court therefore denied the defendant's motion to dismiss.

Honeywell. Finally, Plaintiffs cite Judge Leung's decision on a discovery dispute in *Honeywell Int'l Inc. v. ICM Controls Corp.*, No. 11-cv-569 (JNE/TNL), 2013 WL 12139845, at *6 (D. Minn. Sept. 24, 2013) for the proposition that "alternative designs are reasonably calculated to lead to the discovery of admissible evidence." Pl. Mem. at 10. Even putting aside that this decision cites the old "reasonably calculated" discovery

standard rather than the current relevance standard, this was a dispute involving allegations of patent, copyright, and trademark infringement. It has no bearing here.

C. The Court Should Not Defer The Relevance Issue to Summary Judgment.

This Court may be tempted to allow Plaintiffs to proceed with their burdensome discovery of VitaHEAT and defer the legal question of whether the UB3 can qualify as a feasible safer alternative design until summary judgment.[7] It should not do so. Whether a product identified by the plaintiff can qualify as a safer alternative feasible design is a *threshold* question for whether a design defect claim can proceed, and therefore whether discovery concerning that alternative product should occur at all. Courts frequently dismiss design defect claims that identify a different product – including a different product also sold by the defendant – as a safer alternative feasible design. *See, e.g.*, *Massa*, 2012 WL 956192, at *7 (granting motion to dismiss as discussed *supra*); *Bertini v. Smith & Nephew, Inc.* 2013 WL 6332684 (E.D.N.Y. July 15, 2013) (granting motion to dismiss because plaintiff failed to plead facts to plausibly suggest that it was feasible to design the device used in their cases in a safer manner; it was not enough to allege that defendant sold other versions of the R3 liner that were less dangerous than the one used in plaintiff's surgery"); *Salvio v. Amgen Inc.*, 2012 WL 517446 (W.D. Pa. Feb. 15, 2013)

[7] In *Burks*, 2010 WL 1576779, Judge Tunheim allowed discovery to proceed despite his conclusion as a matter of law that "liquid infant formula is a different product entirely than powdered infant formula." VitaHEAT and 3M respectfully submit that such a tack – allowing discovery on legally insufficient claims – would today be inconsistent with the relevance and proportionality requirements of amended Federal Rule 26(b)(1).

(granting a motion to dismiss where plaintiff alleged that defendant should have sold alternative drugs to Enbrel).

Based on all of the foregoing case law, it is a ***certainty*** that Plaintiffs will not be able to offer the UB3 at trial as a safer alternative feasible design to the Bair Hugger system. For all these reasons, this Court should sustain VitaHEAT and 3M's relevance objection to Plaintiffs' subpoena.

II. Even If There Were Some Minimal Relevance (And There Is Not), It Is Outweighed By the Burden and Risk of Competitive Harm to VitaHEAT.

Far outweighing any non-existent benefit to the litigation, compliance with Plaintiffs' subpoena would cause undue burden to VitaHEAT and could also cause irreparable competitive harm. *See* Fed. R. Civ. P. 45(d)(3)(A), Fed. R. Civ. P. 26(b)(1); *Miscellaneous Docket Matter No. 1 v. Miscellaneous Docket Matter No. 2*, 197 F.3d 922, 925 (8th Cir. 1999) (even if discovery may be relevant, "discovery is not permitted where no need is shown, or where compliance would be unduly burdensome, or where harm to the person from whom discovery is sought outweighs the need of the person seeking discovery of the information.")

The requests in Plaintiffs' subpoena seek vast amounts of documents related to issues with no relevance to the *Bair Hugger* litigation. Plaintiffs seek *all* documents about the design, testing, regulatory submissions, and marketing of the UB3 systems; and *all* documents related to communications with non-parties and 3M related to "patient warming" generally. As explained in the Declaration of William T. Renwick, responding to these requests would require the full-time efforts of nearly 30 percent of VitaHEAT's

work force for at least two to three weeks, even with the assistance of outside counsel. A small business like VitaHEAT cannot withstand that level of disruption. Plaintiffs have simply refused to meet-and-confer with VitaHEAT to narrow their requests to a manageable set of documents – a stark contrast to 3M's efforts over several months to meet-and-confer with Augustine and narrow its requests in order to reduce Augustine's burden to comply.

In addition, Plaintiffs have refused to address VitaHEAT's serious concerns about exposure of their confidential information to a key conductive warming competitor, Dr. Augustine and his HotDog system. This Court is well aware of the ongoing collaborative relationship between the Kennedy Hodges firm – which issued the subpoena to VitaHEAT – and Dr. Augustine. Plaintiffs' unwillingness to address this concern just underscores VitaHEAT's concern about the possibility for exposure of its sensitive business information to its competitor.

For these additional reasons, the Court should deny Plaintiffs' motion.

CONCLUSION

Plaintiffs' sole basis for arguing that their discovery of VitaHEAT is relevant is their assertion that VitaHEAT's UB3 system is a feasible safer alternative design to the Bair Hugger system. As a matter of law, that cannot be so. The UB3 is a substantially different product that employs a fundamentally different technology, and the Bair Hugger system could not incorporate the UB3's technology without itself becoming a fundamentally different product than it is. In addition, this Court cannot ignore VitaHEAT's burden and confidentiality objections. Plaintiffs' extraordinarily broad

subpoena threatens to tie up more than one-third of VitaHEAT's workforce, and potentially expose its sensitive documents to VitaHEAT's competitor and Plaintiffs' counsel's ally, Scott Augustine – all for no benefit to the litigation. For all of these reasons, the Court should deny Plaintiffs' motion.

Dated: February 16, 2017

Respectfully submitted,

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